Supreme Court, U.S.
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No. 93-1172

In The

Supreme Court of the United States

October Term, 1993

JAMES ALBERT ELKINS, SR., MARY JO ELKINS,
as parents and natural guardians of
JAMES ALBERT ELKINS, II,

Petitioners,

v.

RICHARDSON-MERRELL, INC.,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF OF RESPONDENT RICHARDSON-MERRELL, INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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February 21, 1994

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CORPORATE AFFILIATIONS OF RESPONDENT

Respondent, Richardson-Merrell, Inc., now known as Merrell Dow Pharmaceuticals Inc., is a wholly-owned subsidiary of Marion Merrell Dow Inc., which is approximately two-thirds owned by The Dow Chemical Company. Their subsidiaries and affiliates which have securities in the hands of the public are the following:

The Dow Chemical Company
Arabian Chemical Company Limited
Arabian Chemical Company (Latex) Limited
DowBrands L.P.
DCU/LB Trust
Destec Energy, Inc.
Dexco Polymers
Dow Chemical Iberica S.A.
Fort Saskatchewan Ethylene Storage Limited Partnership
H-D Tech Inc.
Cromarty Petroleum Company Limited
Petroquimica-Dow S.A. (Petrodow)
Dow Chemical Japan Limited
Ulsan Pacific Chemical Corporation
Epoxital S.R.L.
Safechem Umwelt Service GmbH
Dow Corning Corporation
Marion Merrell Dow Inc.
Fort Saskatchwan Ethylene Storage Corporation
Promix System
Dow Kakoh Kabushiki Kaisha
Dow Mitsubishi Kasei Limited
Dow Quimica Argentine S.A.
Anticorrosivos Industriales Limitada
Dow-United Technologies Composite Products Inc.

CORPORATE AFFILIATIONS OF RESPONDENT – Continued

El Dorado Terminals Company
Expandite Essex Pty. Limited
Gurit-Essex A.G.
Etoxilados del Plata S.A.
H.D. Polyurethane Company
Joliet Marine Terminal Trust Estate
Lucky Epoxy Limited
Marisub V, Inc.
Carderm Capital L.P.
Marion Merrell Dow K.K.
P.T. Dow Polymers Indonesia
MDP Holdings Ltd.
P.T. Pacific Indomas Plastic Indonesia
Airco Generon Systems LP
DH Compounding Company
DowElanco
Tritech International
Dow Elanco B.V.
P.T. Pacific Chemicals Indonesia
Generon Systems
Generon Systems A.G.
Sumitomo Dow Limited
Zhejiang Pacific Chemical Corporation

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COUNTER-STATEMENT OF THE CASE

Within the past two years, the Sixth Circuit has twice addressed the quantum of evidence required before a Bendectin plaintiff meets his burden of proof requiring submission of his case to a jury. *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, ___ U.S. ___, 113 S.Ct. 84 (1992); *Lee v. Richardson-Merrell, Inc.*, No. 91-5369, *slip op.* (6th Cir. April 22, 1992), 961 F.2d 1577 (table), 1992 W.L. 92750, *cert. denied*, ___ U.S. ___, 113 S.Ct. 197 (1992) (attached hereto as Appendix D).[1] In each of these cases, the Sixth Circuit concluded that the evidence proffered by those plaintiffs was "simply inadequate . . . [to] permit a jury to conclude that Bendectin more probably than not causes limb defects." *Turpin*, 959 F.2d at 1360.[2] The Sixth Circuit in this case reached the same conclusion based upon evidence identical in all material respects to that which was submitted by plaintiffs in the earlier cases. (A2, n.1)

I. Merrell Dow Pharmaceuticals Inc. ("Merrell Dow") manufactured and marketed Bendectin from 1956 to 1983.

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[1] Because the Sixth Circuit's Opinion in *Lee* is unpublished, Respondent has provided a copy of the Opinion in an Appendix to its Brief. Respondent has continued the numbering of this Appendix as if it continues from Petitioners' Appendix. Petitioners' Appendix is incorporated by reference herein so that citations to A1-A16 are to Petitioners' Appendix. All other cites are to Respondent's Appendix.

[2] *See also, Lee v. Richardson-Merrell, Inc.*, at A20:

> We conclude that a finding of a causal relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in *Turpin* . . . .

Bendectin was an antinauseant, available only by prescription, for use by pregnant women to treat "morning sickness," the nausea and vomiting frequently associated with pregnancy.

As the leading treatment for morning sickness, Bendectin was prescribed in as many as 25% to 30% of all United States pregnancies. An estimated 33 million women world-wide took Bendectin during pregnancy. This broad and long term use of the product, combined with the common occurrence of birth defects in the general population, assured, merely as a matter of background incidence, that many women who had taken Bendectin would bear children with birth defects.[3] These events spawned a monumental tort litigation.[4] Because of enormous litigation costs, Merrell Dow ceased producing Bendectin in 1983, despite the fact that it was, and still is approved for marketing by the Food and Drug Administration.[5]

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[3] *Sheffield*, et al., *"The Creation of Therapeutic Orphans – or What Have We Learnt From The Debendox Fiasco,"* 143 *Med.J. Australia* 143 (1985). In Australia and England, Bendectin was known as Debendox.

[4] *See Turpin v. Merrell Dow Pharmaceuticals Inc.*, 959 F.2d 1349, 1351-52 (6th Cir.), *cert. denied*, 113 S.Ct. 84 (1992); Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301, 318-320, 398-401 (1992).

[5] In 1980, the FDA's Fertility and Maternal Health Drugs Advisory Committee, after studying the relevant literature and conducting a full hearing on the issue, concluded that "there was no increased incidence of birth defects among Bendectin-exposed infants; that there was no need for further animal or epidemiological studies; and that Bendectin should not be withdrawn from the market." The FDA adopted these findings. *See*

II. Petitioners commenced this action in 1990 contending that Mary Jo Elkins'[6] use of the antinauseant drug Bendectin during 1968 and 1969 caused her son, James Albert Elkins, II, to be born with deformities of the metacarpals in both hands and the absence of his lower limbs. At the time Mrs. Elkins was prescribed Bendectin, she also received a prescription for Mycostatin, an antifungal antibiotic, to treat a vaginal infection. Shortly thereafter, an additional medicine, Thorazine, was prescribed to further treat her nausea and vomiting. (JA 69).

After extensive discovery, Merrell moved for summary judgment, contending that there was no admissible evidence sufficient to raise a triable issue of fact as to whether Bendectin causes birth defects in general or, specifically, caused James Elkins, II's birth defects. (JA 70, 98). Merrell supported its motion with summaries of 35 human epidemiology studies published in the world's scientific and medical literature, none of which found a causal connection between Bendectin use and birth defects (JA 111-133), as well as documents from the Food and Drug Administration (JA 134-146)[7] and the Affidavit of Steven Lamm, M.D. (JA 105-110), both of which concluded that there was no causal connection between

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Richardson v. Richardson-Merrell Inc., 857 F.2d 823, 824, 827 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989).

[6] James Albert Elkins, Sr. and Mary Jo Elkins were originally individual parties in this action. Their claims, however, were dismissed with prejudice by stipulation. (A-10).

[7] The FDA documents consisted of the following: FDA Drug Bulletin, Vol. 11, No. 1 (March 1981); FDA Talk Paper, T79-49 (October 1, 1979); FDA Talk Paper, T80-40 (September 17, 1980) and; FDA Talk Paper, T82-45 (June 29, 1982).

Bendectin use and an increased incidence of birth defects. Merrell also cited (and in some instances provided copies of) numerous previous decisions rendered in other Bendectin cases including the opinion in the *Lee* case rendered by the United States District Court for the Western District of Tennessee (JA 88-89), together with Petitioners' motion to consolidate this case with *Lee* which Petitioners admitted involved identical issues of causation and the same expert witnesses. (JA 147-154). Finally, Merrell supplied excerpts of previous testimony of a number of Petitioners' expert witnesses.[8]

Petitioners' opposition to Merrell's motion consisted of a Memorandum of Points and Authorities which was more than 100 pages in length.[9] (JA 158-274). Petitioners did not dispute the accuracy of the summaries supplied by Merrell or the admissibility of *any* of its materials. Petitioners instead supplied several affidavits of purported experts who concluded that Bendectin is capable of causing birth defects.[10]

On March 19, 1992, Magistrate William J. Haynes, Jr., after careful review of the material presented by the

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[8] Excerpts of testimony were provided for, among others, Drs. Palmer and Crescitelli. Memorandum of Law in Support of Defendant Merrell Dow's Motion for Summary Judgment, dated June 21, 1991, at Exhibits 2, 11, 13 and 14. *See, e.g.*, JA 155-156.

[9] Despite the length of this pleading, Petitioner nowhere raises his current assertion that Merrell failed to meet its initial burden under Rule 56(c). Fed.R.Civ.P. 56(c).

[10] These affidavits were, in all material respects, identical to those filed in prior Bendectin cases including *Lee* and *Turpin*.

parties, recommended that Merrell's motion be granted.[11] (JA 50-52). On July 31, 1992,[12] the district court adopted the recommendation. After consideration of the Magistrate's recommendations and the supplemental pleadings filed by the parties, the court held that there was insufficient evidence upon which a reasonable jury could base a finding in favor of plaintiff. (A10-A13).

III. After the original briefing was completed, this Court handed down its decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, ___ U.S. ___, 113 S.Ct. 2786 (1993). Merrell advised the Sixth Circuit of the *Daubert* decision.[13] Petitioner then filed a supplemental "letter brief" arguing, for the first time, that Merrell failed to satisfy its threshold burden to show an absence of a genuine issue of material fact under Rule 56(c). Fed.R.Civ.P. 56(c).

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[11] The District Court had previously referred Merrell's motion to the Magistrate pursuant to 28 U.S.C. § 636 (b)(1)(B). (JA 99).

[12] Prior to the district court's ruling, but before the briefing was completed, the Sixth Circuit affirmed the grant of summary judgment in the *Lee* case (A17). Thus, Plaintiffs' Supplement to his Memorandum of Law in Opposition to Defendant Merrell Dow Pharmaceuticals Inc.'s Motion for Summary Judgment, filed June 2, 1992 (JA 418-420), attempted to address the applicability of the Sixth Circuit's affirmance to Merrell's then pending motion.

[13] In particular, Merrell noted that this Court cited the *Turpin* decision with approval when referring to a trial court's power to use "conventional devices", such as summary judgment, when it determines that "evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true . . . ." 113 S.Ct. at 2798.

In affirming the decision of the district court, the Sixth Circuit ruled that because Petitioners bore the ultimate burden of persuasion on the issue of causation at trial, Merrell was required only to "point out" or "show" the lack of a genuine issue regarding causation.[14] (A5). To meet this burden of "pointing out" or "showing" the lack of a genuine issue, Merrell "had no obligation to support its motion with any affidavits . . . so long as whatever is before the district court demonstrates" the lack of a genuine issue. *Id., citing, Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). After reviewing the voluminous record before the district court, the Sixth Circuit specifically held that "Merrell pointed out the absence of a genuine factual issue on the material element of causation." (A6). Having determined that Merrell's initial burden was met, the Sixth Circuit then reviewed the district court's determination that Petitioners failed to meet their corresponding burden and agreed that Petitioners "failed to demonstrate the existence of a genuine factual dispute regarding causation." (A6).

SUMMARY OF THE ARGUMENT

Petitioners attack the circuit court's ruling on a purely procedural ground raised for the first time at the circuit court level. They contend that the Sixth Circuit erroneously determined that Respondent had met its burden, under Rule 56(c), to "show that there is no genuine

[14] The Sixth Circuit did, however, hold that other issues presented by the Petitioners' were, in fact, waived for failure to raise them in the district court. *See* A7.

issue as to any material fact and that [Merrell] is entitled to judgment as a matter of law . . . . " Fed.R.Civ. P. 56 (c). They allege that the Sixth Circuit found the burden met by a mere "conclusory assertion" that Petitioners could not show an essential element of their case, i.e., causation. But this contention misstates the record before the circuit court, the Sixth Circuit's holding and plainly presents no issue warranting certiorari. As this Court made clear in *Celotex*, a party moving for summary judgment must "show" rather than merely "state" the absence of a genuine issue of material fact. That showing, however, far from requiring submission of affirmative evidence, can be made by identifying the materials in the record, including the non-moving party's materials, demonstrating the non-movant's inability to meet the burden which it faces at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). In other words, the standard requires the moving party to do the work of *identifying* the relevant record material. Not surprisingly, the decision of the Fourth, Fifth and Eleventh Circuits cited by Petitioner (Pet. at 2) say nothing different.[15]

Quite simply, nothing in the Sixth Circuit's opinion (or in any other circuit courts' opinion cited by Petitioner) repudiates or departs from that standard. Nor, in fact, does the Sixth Circuit's earlier decision in *Street*, which,

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[15] Notwithstanding Petitioners' contentions, the Court of Appeals for the District of Columbia did not adopt any different standard for Rule 56 in *ACLU Foundation of Southern California v. Barr*, 952 F.2d 457 (D.C. Cir. 1991). Rather, the circuit court addressed, in *dicta*, the certain special problems associated with intelligence information relating to surveillance under the Foreign Intelligence Surveillance Act, 50 U.S.C. §§ 1801-1811.

in any event, was not cited in this case on the legal standard governing summary judgment.[16] Accordingly, this case presents only a fact specific application of established summary judgment standards – an issue unworthy of this Court's attention.

ARGUMENT

I. This Court Should Deny *Certiorari* Because This Case Does Not Present Issues Upon Which There Is Conflict Among The Circuit Courts.

Petitioners' contend this Court's decision in *Daubert* requires a finding that the sole affidavit filed in support of Merrell's motion for summary judgment (that of Dr. Lamm) be held inadmissible. Since, according to Petitioners, Merrell's motion is unsupported by other record evidence, Merrell's motion essentially consists of a "mere conclusory assertion" that Petitioners cannot prove their case. *Petition* at 4. According to Petitioners, the Sixth Circuit nevertheless granted Merrell's motion because it allegedly reads *Celotex* as permitting a movant to merely assert the nonmoving party cannot produce sufficient

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[16] The Sixth Circuit did cite *Street v. J.C. Bradford & Co.*, 886 F.2d 1472 (6th Cir. 1989) in resolving Petitioners' argument that the district court's grant of summary judgment violated their right to a jury trial guaranteed by the Seventh Amendment (A8) – an argument not presented by this Petition. In doing so, the Sixth Circuit merely approved this Court's direction in *Matsushita Elect. Indus. Co.,-Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) "to consider the record as a whole on summary judgment and decide whether any rational juror could decide the disputed factual issue in the nonmovant's favor." (A8).

evidence to go to a jury and thereby challenge the non-movant to "put up or shut up" on a critical issue. *See Petition* 1-2, *citing, Street v. J. C. Bradford & Co.*, 886 F.2d 1472, 1478 (6th Cir. 1989).

In discussing and resolving Petitioners' challenge under *Daubert*, to Merrell's alleged failure to meet its Rule 56(c) burden, the Sixth Circuit neither mentions nor relies upon the *Street* "put up or shut up" approach. (A5-A6) Thus, this case does not present a vehicle for determining the soundness of an alleged "put up or shut up" approach.

In fact, Merrell's motion in this case was obviously supported by far more than a "mere conclusory assertion" that plaintiffs could not prove their case. The motion was amply supported by the Lamm affidavit, the FDA documents, the summaries of the published literature, other opinions and Petitioners' own admission that their causation evidence was the same as that which was proffered in the *Lee* and *Turpin* cases, an admission that the Sixth Circuit specifically confirmed. A2, n.1. (". . . identical in all material respects to the evidence . . . [in *Turpin*]").

Even the admission by itself – specifically listed as a type of evidence proper under Rule 56(c) – would be enough to sustain Merrell's burden. *See*, 10A C. Wright, A. Miller & M. Kane, Federal Practice and Procedure § 2724, pp. 52-54 (2nd ed. 1983) (hereinafter "Wright & Miller").[17] But, it is clear that *all* of the material was

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[17] "Rule 56(c) also permits the court to consider any admission on file. The quoted words make it clear that the admissions

properly part of Merrell's showing. *See Celotex*, at 323 ("whatever is before the district court"); Wright & Miller, §§ 2721, at p. 40,[18] § 2724, at p. 73.[19]

The Sixth Circuit was therefore correct in readily concluding that Merrell met its burden under Rule 56 to show on the record that Petitioners had insufficient evidence to meet their burden of proving causation.

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need not be pursuant to rule 36: they may have emerged at the pretrial conference, have occurred during the oral argument on the motion, have been made in connection with one of the other discovery procedures or have their roots in a joint statement or stipulation of counsel."

[18] ("[T]he particular forms of evidence mentioned in [Rule 56] are not the exclusive means of presenting evidence on a Rule 56 motion.")

[19] ("The cases indicate that there are a variety of materials not expressly mentioned in Rule 56 that a federal court may consider on a summary judgment motion") (citations omitted).

CONCLUSION

The petition for writ of *certiorari* should be denied.

Respectfully submitted,

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APPENDIX D

NOT FOR PUBLICATION

No. 91-5369

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

RONNIE LEE and MACKEY LEE, Individually and as Parents and Natural Guardians of MICHAEL LEE, a Minor,

Plaintiffs-Appellants,

v.

RICHARDSON-MERRELL, INC., A Delaware Corporation,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSE [sic]

(Filed Apr. 22, 1992)

NOT RECOMMENDED FOR FULL-TEXT PUBLICATION

Sixth Circuit Rule 24 limits citation to specific situations. Please see Rule 24 before citing in a proceeding in a court in the Sixth Circuit. If cited, a copy must be served on other parties and the Court. *This notice is to be prominently displayed if this decision is reproduced.*

BEFORE: MARTIN and SUHRHEINRICH, Circuit Judges; and PECK, Senior Circuit Judge.

PER CURIAM. This is an appeal in a diversity action brought under Tennessee law by plaintiffs Ronnie and

Mackey Lee on behalf of their minor child, Michael Lee, against defendant Richardson-Merrell, Inc. ("Merrell"). The Lees contend that Michael's birth defect, a limb reduction defect, was caused by his mother's ingestion during pregnancy of the Merrell product Bendectin. The district court granted summary judgment in favor of Merrell. We affirm.

The plaintiffs allege that Mackey Lee ingested the anti-nausea drug Bendectin on or about September 21, 1973, when she was about seven weeks pregnant with Michael Lee. Michael was born on March 27, 1974, with various limb deformities characterized by shortness and webbing of his fingers and generalized smallness of his hands. The Lees assert that Mackey Lee ingested no other drugs during this period of time that Michael's birth defects are not genetic. The plaintiffs submit that Mackey Lee's ingestion of Bendectin during the time that Michael's limbs were beginning to develop was the proximate cause of Michael's birth defects.

Merrell filed a motion for summary judgment alleging that all relevant epidemiological studies indicate that there is no statistically significant link between the use of Bendectin and the type of birth defects suffered by Michael Lee. Merrell asserted that these human epidemiological studies comprised the only competent evidence on the issue of whether Bendectin is a teratogen (a substance capable of causing birth defects).

The Lees submitted contrary scientific testimony which concluded that Bendectin was a teratogen based on (1) chemical structure analyses of Bendectin's antihistamine component doxylamine succinate; (2) *in vitro*

(test tube) studies; (3) *in vivo* (animal) studies; and (4) criticism and reanalysis of various epidemiological studies submitted by Merrell. The Lees argued that their scientists possessed the requisite "knowledge, skill, training, education,and experience" to qualify as experts and that their opinions were based on "the type of data generally and reasonably relied upon by experts in the particular field."

After a thorough review of the proffered testimony, the district court determined that the Lees had not produced sufficient evidence of causation to preclude summary judgment. The appeal followed.

The Lees offered the opinion of seven experts to establish that Bendectin was a teratogen and that Mackey Lee's ingestion of Bendectin caused Michael Lee's birth defects. These scientists possess expertise in fields ranging from developmental biology and reproductive epidemiology to biostatistics and pharmacology. Collectively, the Lees' experts would offer testimony concluding that to a reasonable degree of certainty Bendectin is a associated with limb defects.

In response to this expert testimony, defendant Merrell submits that human epidemiological studies demonstrate an absence of any significant causal link connecting Bendectin use with birth defects. To support this position, Merrell submitted summaries of over thirty epidemiologic studies, none of which demonstrate a connection between Bendectin and birth defects.

As noted above, the Lees' experts rely on chemical structure analyses of doslyamine succinate, *in vitro* and *in vivo* studies and reanalyses of human epidemiological

data. We conclude that finding of a causal relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best in light of this court's recent opinion in *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-5690 (6th Cir. March 11, 1992). In *Turpin*, another panel of this court reviewed the scientific data on Bendectin in great detail and concluded that the evidence presented by the plaintiffs' experts fell short of showing that "Bendectin more probably than not causes limb defects in children born to mothers who ingested the drug at prescribed doses during pregnancy." Slip op. at 24.

The evidence presented by the Lees in the instant case is identical in all material respects to the evidence relied upon by the plaintiffs in *Turpin*. *Compare* Jt. App. 2040-2092 (Affidavits of Drs. Glasser, Gross, Crescitelli and Swann) *with Turpin*, slip op. 9-22 (identical testimony by affidavit). The plaintiffs' experts in both cases are the same. In both cases, the experts reach their conclusions based upon their reanalyses of prior epidemiological studies and the use of animal studies to predict Bendectin's teratogenic effects in human beings. For the reasons stated in *Turpin*, we view this testimony as unable to bridge "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue of human birth defects. . . . " Slip. op. at 24. In short, the plaintiffs' scientific evidence, taken as whole, fails to create a genuine issue of material fact. Consequently, summary judgment for the defendant on the issue of causation was appropriate. *See Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479 (6th Cir. 1989) (respondent must

produce evidence supporting every essential element of his or her case to prevent summary judgment).

We have examined the entire record in this case and we can find no material difference between this case and *Turpin*. We further find that without such evidence the plaintiffs cannot prove that Michael Lee's birth defects were caused by his mother's ingestion of Bendectin. Given this conclusion we need not address Merrell's remaining arguments or the district court's alternative holding excluding plaintiffs' evidence. Accordingly, for the reasons as fully stated in this court's opinion in *Turpin*, the district court's grant of summary judgment in favor of defendant Merrell is AFFIRMED.

A TRUE COPY

Attest:

LEONARD GREEN, Clerk

By /s/ Diane Schnur
Deputy Clerk